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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,769	02/09/2004	Charles E. Dinkler	OHM-182A	8827
C. Richard Eby	7590 08/11/200	EXAMINER		
2700 Carew Tower			EREZO, DARWIN P	
441 Vine Street Cincinnati, OH			ART UNIT	PAPER NUMBER
	·		3773	
			MAIL DATE	DELIVERY MODE
			08/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/774,769	DINKLER, CHARLES E.			
Office Action Summary	Examiner	Art Unit			
	Darwin P. Erezo	3773			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ Responsive to communication(s) filed on <u>09 Ma</u>	av 2008				
	action is non-final.				
·=	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
ologod in accordance with the practice and in	x parte gaayle, 1000 G.B. 11, 10	0.0.210.			
Disposition of Claims					
 4) ☐ Claim(s) 1-17 and 25-30 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) 27-30 is/are allowed. 6) ☐ Claim(s) 1-10,15-17,25 and 26 is/are rejected. 7) ☐ Claim(s) 5 and 11-14 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. 					
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 					
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	ite			

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DETAILED ACTION

Election/Restrictions

1. The applicant's traversal of the restriction requirement mailed on 4/10/08 is persuasive and the restriction has been withdrawn.

Claim Objections

- 2. Claims 5 and 11 are objected to because of the following informalities:
 - -Claim 5 is dependent upon claim 1 but recites the limitation of "the engagement shaft", which is a limitation of claim 4 and not of claim 1. Therefore, claim 5 should depend upon claim 4 instead of claim 5.
 - -Claim 11, line 2, "to limit slidable motion of the engagement" should read as --to limit slidable motion of the engagement shaft--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 4. Claims 1-10, 15, 16 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,629,982 to Day et al.

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<u>Claim 1</u>: Day discloses an apparatus capable of use with a radiolucent skull clamp supporting a head of a patient comprising:

-a skull pin assembly capable of being mounted on the skill clamp (via handle 52) comprising a skull pin **30**;

-a pin load applicator adapted to be removably connectable to the skull pin assembly and comprising:

- -a loading shaft **56**,
- -a biasing element 58 operable to apply a force on the loading shaft, and
- -a load force indicator **72** connected to the loading shaft (Fig. 3) and providing an indication of the force being applied by the skull pin contacting the head of the patient, the loading shaft, the biasing element and the load force indicator (all shown in Fig. 4) is formed to be a unitary component that is connectable and removable form the skull clamp as a single component (elements 56, 58 and 72 are formed as a single unit prior to the threaded connection to the rocker arm/skull clamp; col. 6, II. 51-60),

wherein the pin load applicator being movable to adjust the force applied by the skull pin contacting the head of the patient, and thereafter, the pin load applicator being fully capable of being removable from the skull clamp without changing the force being applied by the skull pin contacting the head of the patient. The skull pin assembly and the pin load applicator can be arranged so that enlarged outer section 33 of the skull pin assembly is resting against the opening of the outer end 48 of the rocker arm. Therefore, when the pin load

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applicator unscrewed from the rocker arm, the skull pin assembly will remain against the opening of the outer end **48** of the rocker arm and the patient's head.

<u>Claim 2</u>: With the arrangement recited above, the skull pin assembly can be fixed against the opening of the outer end **48** of the rocker arm and the patient's head.

<u>Claim 3:</u> The skull pin assembly moves linearly in cooperation with the pin load applicator.

<u>Claims 4, 5, 10:</u> The skull pin assembly further comprises an engagement shaft **35** cooperable with the pin load applicator; wherein the skull pin assembly is fully capable of sliding within the opening of the skull clamp or rocker arm.

<u>Claims 6, 7</u>: The biasing element is a spring that applies a force against the loading shaft in a direction toward an interior of the skull clamp.

Claim 8: The device further comprises a hollow adjustment screw **54** connected to a handle **52**, which is viewed as an insert adapted to receive and support the skull pin assembly.

<u>Claim 9</u>: The skull clamp or rocker arm **44** has a bore. It is noted that the skull clamp is not positively recited in the claims and do not provide any additional structural limitations to the invention.

<u>Claim 15</u>: The pin load applicator (comprising elements 56, 58 or 72) is threadedly connected to the insert **52** via screw **64**.

<u>Claim 16</u>: The loading shaft has a plunger **57**.

Claim 25: See claim 1 and the following: Day discloses a knob **52** with a threaded portion **54**.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. Claims 17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al.

Day discloses all the limitations of the claims, including an additional skull pin assembly as shown in Fig. 1, except for the materials used to form the device.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the skull pin be made of radiolucent material since the examiner takes Official notice that the use of radiolucent skull pins is well known in the art, especially since the skull clamps are also known to be radiolucent. It would also have been obvious to make the pin load applicator be made of non-radiolucent materials because it is not used as a reference point during imaging.

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Allowable Subject Matter

8. Claims 27-30 are allowed.

9. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject

matter:

As to claim 27, the prior art of record fails to teach or render obvious an apparatus for use with a skull clamp, the apparatus comprising, inter alia, a skull pin assembly comprising a skull pin and a holder; a lock mounted on and adjustable relative to the holder to prevent movement of the skull pin; and a pin load applicator that is removably connected to the skull pin assembly and movable to adjust the force applied by the skull pin contacting the head of the patient, so that the lock can then be adjusted relative to the holder so as to maintain said applied force, and thereafter the pin load applicator being removable from the skull pin assembly without changing said applied force being applied by the skull pin contacting the head of the patient.

As to claims 11-14, the prior art of record fails to teach or render obvious an apparatus for use with a skull clamp, the apparatus comprising, inter alia, a skull pin assembly comprising a lock nut threaded on an inner end of the engagement shaft of the skull pin assembly to limit slidable motion of the engagement shaft.

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Response to Arguments

11. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new interpretation of the Day ('982) reference, which was necessitated by the applicant's amendments to the claims.

Conclusion

- 12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/ Primary Examiner, Art Unit 3773